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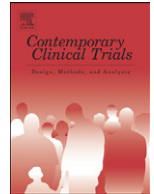
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Conducting qualitative research within Clinical Trials Units: Avoiding potential pitfalls

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ABSTRACT

The value of using qualitative research within or alongside randomised controlled trials (RCTs) is becoming more widely accepted. Qualitative research may be conducted concurrently with pilot or full RCTs to understand the feasibility and acceptability of the interventions being tested, or to improve trial conduct. Clinical Trials Units (CTUs) in the United Kingdom (UK) manage large numbers of RCTs and, increasingly, manage the qualitative research or collaborate with qualitative researchers external to the CTU. CTUs are beginning to explicitly manage the process, for example, through the use of standard operating procedures for designing and implementing qualitative research with trials. We reviewed the experiences of two UK Clinical Research Collaboration (UKCRC) registered CTUs of conducting qualitative research concurrently with RCTs. Drawing on experiences gained from 15 studies, we identify the potential for the qualitative research to undermine the successful completion or scientific integrity of RCTs. We show that potential problems can arise from feedback of interim or final qualitative findings to members of the trial team or beyond, in particular reporting qualitative findings whilst the trial is on-going. The problems include:

1. Unplanned modifications of the trial intervention during the full RCT
2. Selection bias and threats to external validity
3. Unblinding of group allocation
4. Breach of participant anonymity and confidentiality in small RCTs
5. Unplanned modifications of the trial processes and procedures
6. Threats to completion of recruitment, retention and outcome measurement.

We make recommendations for improving the management of qualitative research within CTUs.

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Abbreviations: NIHR, National Institute for Health Research; QM-SOP, standard operating procedure for undertaking qualitative research; TMG, Trial Management Group; TSC, Trial Steering Committee; UKCRC, UK Clinical Research Collaboration

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1. Introduction

The UK Medical Research Council framework recommends that both qualitative and quantitative methods are necessary to evaluate complex interventions [1]. Qualitative research can be used concurrently with a pilot or full randomised controlled trial [2–4]; for example, to optimise recruitment and informed consent strategies, to identify the acceptability of the

intervention or the trial protocol, to provide insights into processes of behaviour change (mediators and moderators) or to help understand trial findings [1,5–7]. Recently, a systematic mapping review of published qualitative research carried out with randomised controlled trials (RCTs) was completed [8]. From this exercise an empirically-based framework was developed for the different aspects of RCTs addressed by qualitative research. The framework covers five broad categories: the intervention being tested, trial design and conduct, trial outcomes, outcome and process measures and the health condition the intervention was aimed at.

Clinical Trials Units (CTUs) in the United Kingdom (UK) manage large numbers of RCTs and, increasingly, manage the qualitative research, or work with qualitative researchers external to the CTU. CTUs are beginning to explicitly manage this process; for example, one CTU has recently produced a standard operating procedure for undertaking qualitative research (QM-SOP) with trials. The QM-SOP aims to standardise to a degree the processes for developing, conducting, and reporting this qualitative research [9]. In this paper, we reflect further on how to help ensure that qualitative research conducted concurrently with either pilot or full RCTs contributes fully to the conduct of the trial and the interpretation of findings, without compromising the scientific validity of the trial. We make recommendations not previously addressed in the published literature which focus specifically on reporting the progress and findings of qualitative research whilst a trial is ongoing.

2. Methods

The reflections we present here are based on the experiences of two UK Clinical Research Collaboration (UKCRC) registered CTUs of conducting qualitative research within their units. Each CTU employs between 40 and 50 staff, including trialists, statisticians and staff who have qualitative research skills. Whilst both CTUs specialise in RCTs of complex health interventions (funded in the main by the National Institute for Health Research (NIHR)), the portfolio of work in each is broad-ranging and includes the evaluation of medicinal products and various health technologies which are not limited to specific clinical conditions or populations. The aims of the qualitative research undertaken in both CTUs cover those previously described [8], including addressing the intervention and trial conduct processes. Three of this paper's authors have leading roles within these units and three have undertaken qualitative research with these as well as other CTUs. Our viewpoints are based on extensive experience of being closely involved with the design and implementation of qualitative research with publicly funded multi-centre RCTs.

We reviewed 15 studies currently in progress or recently completed in the two CTUs (Table 1). Nine of these studies involved a full RCT conducted with concurrent qualitative research and five involved a pilot RCT conducted with concurrent qualitative research. One study was qualitative research undertaken prior to an RCT to inform the conduct of the RCT. The studies were selected to help identify issues specific to undertaking qualitative research concurrently with RCTs. Our review comprised assessment of the following: the

Table 1
Studies undertaken in two CTUs where qualitative research was conducted with RCTs.

Trial identifier	Phase	Intervention	Focus of the qualitative research	^a Timing of reporting of the qualitative research
A	^b External feasibility study (in preparation for Study B)	Clinical treatment	Intervention content and delivery	Early (i.e. prior to the main trial commencing)
B	Full RCT	Clinical treatment	Intervention content and delivery	Mid-RCT
C	Full RCT	Clinical treatment	Intervention content and delivery Trial design, conduct and processes	Mid-RCT
D	Full RCT with internal pilot trial.	Public health	Intervention content and delivery	Late
E	Full RCT	Public health prevention	Intervention content and delivery	Mid-RCT
F	Full RCT with internal pilot trial.	Public health prevention	Intervention content and delivery	Late
G	^b External pilot trial	Clinical treatment	Intervention content and delivery Trial design, conduct and processes	Early (i.e. prior to the main trial commencing)
H	^b External pilot trial	Clinical treatment	Intervention content and delivery Trial design, conduct and processes	Early (i.e. prior to the main trial commencing)
I	^b External pilot trial	Clinical treatment	Intervention content and delivery Trial design, conduct and processes	Early (i.e. prior to the main trial commencing)
J	^b External pilot trial	Clinical treatment	Intervention content and delivery Trial design, conduct and processes Target condition	Early (i.e. prior to the main trial commencing)
K	Full RCT	Clinical treatment	Intervention content and delivery	Mid-RCT
L	Full RCT	Clinical treatment	Intervention content and delivery Trial design, conduct and processes Target condition	Mid-RCT
M	Full RCT	Clinical treatment	Intervention content and delivery	Mid-RCT
N	^b External pilot trial	Clinical intervention	Trial design, conduct and processes	Early (i.e. prior to the main trial commencing)
O	Full RCT	Clinical treatment & Prevention	Intervention content and delivery	Mid-RCT

^a See Table 2 for description of terms.

^b The terms external and internal pilot and feasibility studies are used as defined by previous authors [10] i.e. a pilot trial is a smaller version of the main trial that is run to test whether the components of the main trial can all work together. An internal pilot will be the first phase of the main trial and data from the pilot phase may contribute to the final analysis. An external pilot is a study distinct from, and conducted prior to, the main trial and the data are analysed separately.

purpose of reporting the qualitative research; the processes by which progress and findings from the qualitative research and RCT were reported to the staff involved in conducting the RCT, conducting the qualitative research and overseeing the whole study; and the timing of reporting the qualitative research in relation to the conduct of the RCT e.g. whether the findings were intended to be disseminated before the RCT closed.

3. Results

The 15 studies are described in Table 1. There was variation between studies in terms of: (1) the *purpose* of reporting the qualitative findings to wider team members whilst the trial was on-going; (2) the *processes* of reporting; and, (3) the impact of the *timing* of reporting the qualitative research.

3.1. The purpose of reporting the qualitative findings whilst the trial is on-going

In Study A (see Table 1), qualitative research was undertaken prior to the full RCT to determine participants' views of the intervention. Interim findings about the intervention were fed back to the chief investigator and clinical investigators delivering the intervention at weekly meetings without any planned purpose to attendance of the qualitative researcher at the meetings. We identified two potential problems with this feedback in practice. First, due to the qualitative study's small sample size and the distinctive clinical features of patients, it was very difficult to maintain participant confidentiality. Hence, by being given access to emerging qualitative findings, there was the possibility that clinicians providing care could identify the patients who had been interviewed and could become aware of the views they had expressed. The problem here is that study participants agreed to discuss their experiences with the researcher in the understanding that the findings would be anonymised but anonymity was difficult to maintain in verbal feedback meetings with clinical collaborators. In making this observation, we do recognise that this is a potential problem in any qualitative study and is not specific to qualitative studies undertaken to inform RCTs. The second problem was that some of the participants who took part in qualitative research reported struggling to adhere to the intervention due to poor clinical support and lack of information on initiation of the treatment. Clinicians providing the intervention changed their clinical practice during the pilot study to address these problems. Changes to an intervention may be acceptable during a pilot trial [1] but are not acceptable during a full trial (Study B) when the intervention should be developed and stable. Even during a pilot study, continuous modification of the intervention on the basis of feedback from small numbers of participants could make it difficult to be certain about the nature of the intervention being evaluated.

In contrast to Study A (above), where interim feedback of qualitative research findings occurred without planned purpose, in Study C, where qualitative research was undertaken concurrently with a full RCT, the purpose of the regular interchanges between the qualitative researchers and the RCT team was planned in the qualitative research protocol. The purpose of feedback of the qualitative findings whilst the trial was in progress was to allow the qualitative study to adapt to the needs of the trial and the trial processes to also be adapted if necessary.

In this particular study, difficulties with follow-up data collection were identified in the course of the trial and the interview topic guide was adapted to explore participants' views about this issue to enable modification of follow-up data processes.

3.2. The processes of reporting

In Study C (above), senior staff in the CTU recognised that feedback of the qualitative findings to the whole Trial Management Group (TMG), which included staff delivering the intervention, might influence intervention delivery when this was not intended. In response to this, a sub-group of the TMG was established to engage with the findings of the qualitative research during the course of the RCT and to decide on how to implement these findings in accordance with the trial protocol. The qualitative research revealed that participants were not engaging with the study intervention as expected. The establishment of the subgroup allowed a forum for discussion of issues, such as safety, whilst keeping the information from TMG members who were delivering the intervention and who might have had an interest in maximising the effectiveness of the intervention.

In other studies (e.g. D and F) there was an implicit assumption that the qualitative findings would be revealed at the end of the trial to inform interpretation of the trial results, without any explicit thought given to the potential benefits of ongoing feedback. In these studies, the qualitative research tended to appear lower down the TMG meeting agendas than trial matters, and, when the qualitative research was discussed in these meetings, discussions tended to focus on progress of participant recruitment for the qualitative research. There may have been benefits to having ongoing reporting of the findings of the qualitative research which were not explored.

3.3. The effect of timing of reporting the qualitative research on the RCT

There was variation between studies regarding the timing of completion of the qualitative research in relation to the completion of the RCT (see Table 2). For external pilot trials (Studies G, H, I & J), the qualitative research was both completed and reported 'early' in relation to the full RCT; that is, before the full RCT began. High priority was given in the TMG to reporting the qualitative findings because acceptability of the intervention and views on trial processes were key outcomes of these pilot studies. As the qualitative research and pilot trial data collection (e.g. on participant recruitment and retention rates) completed concurrently, the timing of dissemination was uncontroversial because the potential influence of the qualitative research on the conduct of the full trial or the delivery of the intervention was built into the protocol for the full RCT. In some studies, particularly those where the full trial's follow-up period was longer than a year, the qualitative research was planned to be completed much earlier than the trial (e.g. Studies K, E and C) – indicated as 'mid-RCT' in Table 2. This timing was identified as having potentially detrimental implications for the successful completion of the trial in two studies. This is because there was a conflict between the desire to disseminate findings from the qualitative research quickly and the concern expressed by TMG members about the impact this might have on the on-going trial. For example, in Study K

Table 2

Timing of reporting the qualitative research.

Timing in relation to the main trial	Advantage	Risks
Early – before participant recruitment in the main trial or in pre-trial pilot and feasibility studies	Informs recruitment strategy Informs intervention delivery Informs outcome measures	Depends on the aim of the qualitative research but may miss opportunity to get full insight into participants' views & experiences, if the pilot study is small and there is no further qualitative research concurrent with the definitive trial Alters trial protocol e.g. recruitment strategy – affects trial integrity
Mid RCT – whilst recruitment and / or intervention delivery is on going in the main RCT	Concurrent data collection that enables modifications to qualitative research and/or the trial conduct e.g. questions to be expanded/changes in data collection process	
Late – at the end of the main RCT when outcome measures completed	Doesn't impact on trial integrity	Too late to follow up any issues regarding recruitment, adherence etc within the trial. May rely on retrospective accounts which can be subject to recall bias

findings from the qualitative research indicated that the intervention was unpopular with and poorly adhered to by participants. As trial recruitment was still open, there was concern that reporting of these findings to trial staff might compromise recruitment due to de-motivation of the recruiting staff. In Study E, the concern was that putting findings about problems expressed about the intervention into the public domain might lead to demoralisation of participants and affect outcome assessment and attrition. Where reporting of the qualitative research was undertaken mid-RCT and qualitative research staff were on short-term contracts (e.g. Study K), they were not funded towards the end of the trial to help interpret the trial results.

4. Discussion

Timely reporting of interim findings from qualitative research undertaken concurrently with external pilot trials may lead to valuable adaptations to the intervention or the trial protocol during the pilot as well benefitting the subsequent full RCT. Reporting of interim findings whilst a trial is in progress may be helpful but has the potential to damage the integrity of the trial. This may be particularly the case if the qualitative research identifies negative issues about the intervention. Indeed, researchers have previously made calls for process evaluation data committees in community intervention RCTs to make decisions on emerging findings from qualitative research to ensure that data from process evaluations provide a source of insight for the RCT rather than a point of contention [11]. There may even be a case for submission of findings from qualitative studies to Data Ethics and Monitoring Committees where emerging findings indicate potential harm to participants.

COREQ criteria were developed because of the need for a CONSORT-equivalent for qualitative research [12] and are valuable in guiding researchers in reporting qualitative research after study completion. COREQ is intended to be “a formal reporting checklist for in-depth interviews and focus groups” [12] covering important aspects of the study, including the composition of the research team, study methods, study context, findings, analysis and interpretations. There have also been recommendations for reporting the results of qualitative studies carried out alongside trials of complex interventions

within systematic reviews of effectiveness to explain heterogeneity of trial results [13]. However, there is no guidance in relation to communication of findings whilst the trial is in progress. Given that it is recommended that process evaluations (which include qualitative research) are analysed prior to the completion of the RCT analysis [14], we have identified a number of potential risks related to feedback of interim or final qualitative findings to members of the trial team, which may include the chief investigator and those delivering the intervention. These risks and their potential consequences relate to feedback on participants' views of the interventions as well as feedback on participant views of the research procedures.

Feedback regarding participants' views of the interventions may compromise the integrity of the trial in three ways:

First, knowledge of dissatisfaction with, or acceptability of, the intervention may result in attempts by the team (consciously or unconsciously) to adapt or improve the intervention. Such changes may be acceptable as part of a feasibility or pilot trial where development of the intervention is an aim of the study but is unlikely to be acceptable within a pragmatic phase III trial of effectiveness. Improving the intervention during the course of the RCT is problematic in a number of ways. It makes it difficult to replicate the intervention if it is being modified in an ad hoc manner. In addition, the trialled intervention may be nearer to an ideal model rather than the intervention as it can be delivered in routine practice.

Second, knowledge that adherence to, or acceptability of, the intervention differs between specific participant sub-groups (e.g. more severely ill, older or younger participants) may bias participant recruitment in favour of particular groups compromising the external validity of the trial population. Third, none of the trials included in this paper were blinded. However, from the experience of this review and particularly from Study A, we propose that, in a blinded trial, there is potential for feedback of participant views to result in unblinding. It is likely that qualitative researchers could be aware of the group allocation of individual participants or may become aware during the discussion of participants' experiences. It is therefore important that this knowledge is

not unintentionally relayed to the trial investigators. This could occur where participants are known to the investigators and where feedback includes comments on symptoms or characteristics of the intervention which may reveal the group allocation. For example, in a trial involving surgery and sham surgery, discussion of wound healing may reveal the group and discussion of personal or social circumstances may reveal the individual.

Feedback on participant views of the research procedures may compromise the integrity of the trial as it may result in changes to those procedures e.g. to methods of participant recruitment, follow-up or use of outcome measures. There are circumstances where this might improve the trial but the amendments should be explicit and transparent.

Public dissemination of the findings from a qualitative study whilst a trial is on-going could hinder participant recruitment, retention and outcome measure collection. The timing of the qualitative study is an important factor in this respect. Where the qualitative study completes towards the end of the trial then there is unlikely to be conflict about publication [6,15].

In addition, feedback of participant views and experiences may compromise participant confidentiality where the characteristics of the participants or condition or participants' responses to the intervention are idiosyncratic e.g. in a trial of the mode of insulin delivery where an individual participant is known to have a complex set of symptoms such as needle phobia and depression.

4.1. Strengths and limitations

This study is based on 15 studies in 2 CTUs only. The studies reflect a wide range of clinical interventions and populations although specific details of the studies have not been revealed in order to maintain their anonymity. The portfolios of the 2 CTUs are wide ranging and include behavioural, educational, public health, drug and device studies. It is therefore likely that the experiences reported here will be of relevance to other CTUs.

4.2. Recommendations

We recommend that the following be considered and documented where appropriate within the RCT and qualitative research protocols:

Consider whether it is intended that the qualitative research will be used to adapt, amend or refine either the intervention or aspects of trial conduct during the trial. If this is intended, this should be made explicit and the processes by which it will occur should be clear before the trial commences. Consider the following: the timing, process and purpose of reporting of interim and final qualitative findings to the research team and to the public; whether the whole trial team, TMG or Trial Steering Committee (TSC) needs to have access to this information; whether there is potential for reporting to bias the RCT; whether there is potential for reporting to jeopardise the continuing conduct of the trial.

If it is likely that reporting of interim or final findings may be contentious, a sub group should be identified to decide on issues arising from the qualitative research. In cases where the qualitative study and research staff contracts finish early in the trial, a publication committee (containing people unlikely to be biased by exposure to findings) to discuss authorship and if and when findings can be put into the public domain may be essential.

Consideration should also be given to the order of items on the TSC and TMG agenda regarding the trial and the qualitative research to ensure that sufficient time is given to each at relevant stages of the study.

Consider the timing of the conduct of the qualitative research in relation to the RCT and potential impact on the availability of qualitative staff. If qualitative staff are not available at the end of the RCT this may have implications for writing a coherent and integrated report. An RCT with a qualitative study running concurrently should have at least one qualitative researcher as a part of the investigative team who is committed to the study from start to finish. This should be factored into the resources at the proposal submission stage.

5. Conclusion

CTUs registered with the UKCRC are expected to have the infrastructure, procedures and expertise to deliver high quality trials. In reviewing our experience of conducting qualitative research concurrently with trials, we have identified some potential problems which could be avoided by consideration and documentation of issues before starting the trial. These relate particularly to clarifying whether the qualitative research is intended to be used to adapt the intervention or trial protocol and how findings from the qualitative research will be fed back to the trial team and the public.

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